DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 2004

Vanguard Medical Concepts, Inc.
c/o Ms. Heather Crawford
Director of Regulatory Affairs
5307 Great Oak Drive
Lakeland, FL 33815

Re: K011832 - Supplemental Validation Submission
Vanguard Reprocessed Femoral Compression Device
Regulation Number: 21 CFR 870.4450
Regulation Name: Clamp, Vascular
Regulatory Class: II (2)
Product Code: NMF
Dated: September 18, 2001
Received: September 24, 2001

Dear Ms. Crawford:

The above-referenced premarket notification (510(k)) was cleared by the Office of Device Evaluation (ODE) on December 21, 2001. We have received your supplemental validation data as required for reprocessed single-use devices by the Medical Device User Fee and Modernization Act of 2002. After reviewing your supplemental validation data, we have determined the devices listed in the enclosure accompanying this letter are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market these devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (PMA) they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your devices in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's applicable requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in classification for your devices and thus, permits you to legally market the devices. This letter will allow you to continue marketing the devices listed in the enclosure accompanying this letter.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120 (DOEB). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Attachment 1

USCI ® C.R. Bard®, Inc. / RADI Medical Systems AB
Model Number: 017500

OEM Trade Name: FemoStop® Femoral Compression System

Indications for Use

510(k) Number:

Device Name: Vanguard Reprocessed Femoral Compression Device

Indications for Use:

The femoral compression system is indicated for the compression of the femoral artery or vein following catheterization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011832

K011832

DEC 21 2001

510(k) Summary of Safety & Effectiveness

Submitter

Vanguard Medical Concepts, Inc.
5307 Great Oak Drive
Lakeland, FL 33815

Contact

Mr. Mike Sammon, Ph.D.
Director, Research and Development
(863) 683-8680, extension 228
(801) 327-3339 (facsimile)
mikes@safe-reuse.com

Date

June 14, 2001

Device

- Trade Names: Vanguard Reprocessed Femoral Compression Device
  ⇒ USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System
- Common Name: Femoral compression device, groin compressor
- Classification: 21 CFR 870.4450 – Vascular Clamp – Class II
- Product Code DXC

Predicate Device

USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System legally marketed under 510(k) premarket notification K983471

Indications for Use

The femoral compression system is indicated for the compression of the femoral artery or vein following catheterization.

Contra-indications

Femoral compression presents a significant risk for deep vein thrombosis in patients with severe peripheral vascular disease. Femoral artery or vein grafts are also at significant risk for damage with use of this device.

Continued on next page

510(k) Summary of Safety & Effectiveness, Continued

Device Description

The femoral compression device is used to provide compression of the femoral artery for hemostasis management after catheterization. The device is comprised of an arch with an attached sterile pneumatic pressure dome, connector tube, stopcock and belt locks. A woven belt is used to secure the device onto the patient.

In use, the belt is placed under and around the patient's hips and the arch is placed over the patient's groin with the dome atop the puncture site. The belt is attached to the arch via the adjustable belt locks and is tightened. A pneumatic pump and manometer are attached to the stopcock connector. The user controls the mechanical pressure applied to the puncture site by increasing or decreasing air pressure applied to the dome. The arch and belt absorb and distribute the opposing force from the dome.

Vanguard receives previously used compression devices from healthcare facilities; cleans, inspects, tests, repackages and sterilizes the devices; and returns them to the healthcare facility.

Technological Characteristics

The Vanguard reprocessed compression device is essentially identical to the currently marketed OEM compression device. No changes are made to the currently marketed device's specifications and they possess the same technological characteristics. Biocompatibility and performance/functional testing demonstrate that the devices are equivalent and continue to be safe and effective for their intended use.

Test Data

Decontamination and cleaning, sterilization validations and functional/performance and biocompatibility testing demonstrates that the reprocessed devices perform as intended and are safe and effective.

Conclusion

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed femoral compression device is substantially equivalent to the predicate device, the OEM compression device, USCI® C. R. Bard®, Inc., RADI Medical Systems AB FemoStop® Femoral Compression System, under the Federal Food, Drug and Cosmetic Act.